

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16<sup>th</sup> 2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not give any guidance as to what is necessary to 'encourage infection' as claimed. One of ordinary skill in the art would not know what this entails. Applicant's affidavit filed September 16<sup>th</sup> 2009 gives evidence on page 4 that raw table salt provided in the form of a granular paste encourages infection when applied to a wound as claimed. Based on this evidence, Examiner believes the paste of

Bogart et al. when combined with the method of Malodobry, as explained below, can be considered as encouraging infection as claimed.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 9, 14-18, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943).

Regarding claims 1, 5 and 9 Malodobry discloses a method for removing pigments from a pigmented section of skin, comprising: a) puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one solid needle, thereby liberating the pigments and cellular fluids from cells containing said pigments (paragraphs 0043-0048). Malodobry fails to disclose b) bandaging said punctured skin with a pad adapted to absorb said pigments and said cellular fluids, said pad containing one or more materials capable of accelerating a process of migration of said pigments toward an outer layer of the skin, wherein said one or more materials is a salt-based granular paste. Malodobry does disclose using irritants such as sodium chloride to increase exudate and thereby increase the amount of pigments migrating towards the outer layer (this is clearly the intent of using irritants as disclosed in paragraphs 0050-

0052; Examiner notes that the use of irritants is disclosed immediately after Malodobry discloses an intent to use wound exudate to carry pigments to the skin surface; see paragraph 0049). Bogart et al. disclose bandaging a wound with a pad (col. 9, lines 31-35; col. 3, lines 49-54) containing a sodium chloride based granular (col. 4, lines 42-46) paste (a granular gel can be considered as a paste; Applicant has provided experimental data which disclosed the paste as KY gel and salt) to accelerate a process of skin exudate and bacteria migration to an outer layer of skin (col. 4, lines 60-63; col. 9, lines 44-60). It would have been obvious to one of ordinary skill in the art in view of Bogart et al. to have used a pad and paste as claimed for a number of reasons. For example, Malodobry suggests using a sodium chloride irritant but does not give a specific method for applying it. The device and method of Bogart et al. would provide one of ordinary skill in the art with a specific device and method for implementing Malodobry's suggestion of using a sodium chloride irritant to increase wound exudate or drainage. One of ordinary skill in the art would also recognize that the device and method of Bogart et al. would especially enable the exudate to carry the pigments as intended by Malodobry because Bogart et al. teach that their method would cause exudate to sweep bacteria to the outer layer and bacteria are as large or larger than the pigment agglomerates. Regarding claims 2 and 15, Bogart et al. further teach applying one or more antiseptic materials to the punctured skin via the paste (col. 6, lines 27-28 and elsewhere). Regarding claim 3, the paste of Bogart et al., containing the antiseptic materials, can be applied with a pad as explained above. Regarding claim 4, the skin-puncturing device of Malodobry is a tattooing device (paragraph 0046). Regarding

claims 14 and 18, Malodobry discloses injecting aqueous irritant into the pigmented section as claimed (paragraph 0050). It would have been obvious to one of ordinary skill in the art to have maintained this step when modifying with Bogart et al. because one of ordinary skill in the art would recognize that this step could further help the process of pigment migration in addition to the modification described above.

Regarding claim 16, Bogart et al. teach impregnating the pad with the gel (col. 3, lines 49-54) as well as providing antibiotics within the gel as described above. Regarding claim 17, it would have been obvious to one of ordinary skill in the art to have modified the gel/paste as claimed because 1) both Malodobry and Applicant use the same method for creating the wound which should produce a comparable amount of exudate or drainage within a comparable amount of time and 2) Bogart et al. teach absorbing the exudate into the pad/paste as it comes out of the wound (col. 9, lines 31-40).

Regarding claim 21, it would have been obvious to one of ordinary skill in the art to have not provided tattooing ink with the tattooing device in the above method because the method is intended to remove ink already present in the skin. Regarding claim 22, it would have been obvious to one of ordinary skill to remove the pad before damaging the skin. Furthermore, Bogart et al. teach removing the pad and applying another pad designed to protect healthy cells as the wound heals (col. 9, lines 61-63). Regarding claim 23, Bogart et al. teach that the pad should be designed to hold exudate away from the wound (col. 9, lines 36-38). Therefore, it would have been obvious to one of ordinary skill in the art to have removed the pad prior to complete saturation in order to prevent excess exudate from leaking out of the pad and on or around the wound.

Furthermore, it would have been obvious to one of ordinary skill to remove the pad prior to saturation in order to prevent the pad from leaking fluid onto a patient. Regarding claim 24, Bogart et al. teach securing an absorbent dressing or pad (col. 9, lines 31-34; col. 10, lines 46-49). It is old and well-known in the art that absorbent pads are typically applied by wrapping or securing an absorbent pad to a wound with gauze or medical tape. Therefore, it would have been obvious to one of ordinary skill in the art to have secured an absorbent dressing or pad to the wound using by wrapping or covering the pad with gauze or medical tape. Regarding claims 25 and 26, in view of Applicant's affidavit, as explained above, Examiner regards the method and device of Bogart et al. as encouraging infection as claimed. Regarding claim 27, Bogart et al. teach removing the pad after draining a sufficient amount of exudate and then applying a second pad to promote healing as explained above. Bogart et al. also teach applying antibiotics as explained above. It would therefore have been obvious to one of ordinary skill in the art to have provided antibiotics on the second pad because they would promote healing by reducing the chance of infection.

6. Claims 6, 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Garitano et al. (US 2004/0158196).

Regarding claims 6, 7, 19 and 20, Malodobry in view of Bogart et al. disclose the invention as described above. They do not disclose performing the suction of the pigments from said punctured skin with the suction means prior to the bandaging of the punctured skin and during the puncturing of said skin. Garitano teaches the suction of a

solution provided for the removal of tattoos (paragraph 0023). Performing this step during the puncturing step would have been obvious to a person having ordinary skill in the art because prior to this step, there is no fluid to be suctioned. Also, performing this step prior to bandaging would have been obvious because after bandaging, the suction step would not be easily performed. Furthermore, the Examiner notes that no specific advantage was provided for the ordering of these steps so it is considered within the purview of one having ordinary skill in the art to rearrange the order of steps (see MPEP 2144.04 IV C). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the Malodobry removal steps to include Garitano's suction step. Such a modification would draw fluid from the tattoo to further aid in the removal of the pigments.

***Response to Arguments***

7. Applicant's arguments, including the 1.132 Declaration, with respect to pending claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
10/21/09